

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LIXIAO WANG, PAUL J. MILLER,
DANIEL J. HORN and DEBORAH A. FRANK

Appeal No. 2000-0583
Application No. 08/955,984

ON BRIEF

Before COHEN, NASE and BAHR, Administrative Patent Judges.
BAHR, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-5, 14, 15 and 27-30, which are all of the claims pending in this application.¹

¹ Claims 31 and 32 were canceled subsequent to the final rejection in an amendment filed September 7, 1999 (Paper No. 16).

BACKGROUND

The appellants' invention relates to a balloon. An understanding of the invention can be derived from a reading of exemplary claim 1, which is reproduced in the opinion section of this decision, and claim 14, which appears in the appendix to the appellants' brief.

The prior art reference of record relied upon by the examiner in rejecting the appealed claims is:

Levy	4,490,421	Dec. 25, 1984
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The following rejections are before us for review.²

Claims 1-5, 14 and 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Levy.

Claims 27-30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Levy.

Reference is made to the brief and reply brief (Paper Nos. 15 and 18) and the final rejection and answer (Paper Nos. 10 and 17) for the respective positions of the appellants and the examiner with regard to the merits of these rejections.

² The examiner has withdrawn the rejection of claim 29 under 35 U.S.C. § 112, first paragraph (see Paper No. 14).

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the Levy reference, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

Claims 1 and 5

Independent claim 1 reads as follows:

1. An oriented balloon of thermoplastic material prepared by the method of extruding a hollow tube of the thermoplastic material, and subsequently expanding the tube by subjecting the tubing³, while in a mold, to an elevated temperature and an increased interior pressure to produce an oriented balloon, wherein the tube is subjected to a drying step prior to said expanding step, thereby increasing the strength of the balloon relative to a reference balloon prepared in the same manner, except for said drying step.

Claim 1 recites an oriented thermoplastic balloon by listing the process steps used to obtain it. This type of claim is commonly referred to as a product-by-process claim. A product-by-process claim is, however, directed to the

³ It appears that "tubing" should be "tube" for consistency.

product and not to the process used to obtain that product. The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or not patentably distinct from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

In addition to reciting the steps used to obtain the balloon, claim 1 also includes the clause "thereby increasing the strength of the balloon relative to a reference balloon prepared in the same manner, except for said drying step." The terms "strength"⁴ and "manner"⁵ used in this clause lack antecedent basis in the claim and are not expressly defined in appellants' specification.

In proceedings before it, the PTO applies to the verbiage of claims the broadest reasonable meaning of the words in

⁴ Appellants' specification states on page 2 that high tensile strengths are important in angioplasty balloons because they allow for the use of high pressure in a balloon having a relatively small wall thickness. However, the specification does not expressly define "strength" as being tensile strength or burst strength.

⁵ The term "manner" appears on pages 13 and 14 of appellants' specification but is not expressly defined.

their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in appellants' specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

Moreover, absent an express definition in their specification, the fact that appellants can point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation. Id., 127 F.3d at 1056, 44 USPQ2d at 1029.

The term "strength" is ordinarily defined as the power to resist strain, stress, etc.⁶ Of course, a balloon may be subjected to stresses and strains of different types (e.g., mechanical and thermal) and in different directions, such as internal pressure, axial tension, axial compression, torsion, tearing, etc., and will exhibit differing degrees of resistance to these different stresses and strains. As

⁶ Webster's New World Dictionary, Third College Edition (Simon & Schuster, Inc. 1988).

appellants' claims do not specify the type of strength and appellants' specification does not expressly define "strength" and there is no indication in the record that the strength of a balloon is understood in the art to have a more specific meaning, we construe the term "strength" as used in appellants' claims as a measure of resistance to stresses and strains of any type and in any direction.

The term "manner" is defined as a way or method in which something is done or happens.⁷ In the context of appellants' claim 1, it is apparent that "manner" means method, a term which does have antecedent basis in claim 1. Thus, we understand "the same manner" as referring back to the method recited in lines 1-5 of claim 1. In other words, "a reference balloon prepared in the same manner, except for said drying step," as used in claim 1, is a balloon prepared by extruding a hollow tube of thermoplastic material and subsequently expanding the tube by subjecting it to elevated temperature and an increased interior pressure while in a mold to produce an oriented balloon. The reference balloon alluded to in

⁷ Id.

claim 1 must be made from thermoplastic material but need not be prepared, for example, using the same thermoplastic starting material or the same expansion tension, temperature or pressure as the claimed balloon.⁸

In summary, a balloon meets the requirements of claim 1 if it (1) has the same characteristics as a balloon prepared by the method steps recited in claim 1, regardless of the actual method by which it was prepared, and (2) has an increased resistance to stresses or strains of any type and in any direction relative to a reference balloon prepared by the steps recited in claim 1, except for the drying step. With regard to the recited method steps, we note that claim 1 does not recite the starting material more specifically than "thermoplastic material" and does not specify the operating parameters of the extruding, drying or expanding steps, including temperatures, wall thickness (of the tubing or the balloon), moisture content, axial tension, pressure levels, duration and the time delay, if any, between extruding and

⁸ This interpretation is consistent with appellants' Example 3 (Table 3), for example, wherein different tensions were applied during the expansion step for the "comparative" (reference) balloons than for the "invention" balloons.

drying and between drying and expanding. Additionally, the claim language does not preclude additional steps not recited in the claim.

Having ascertained the scope and content of claim 1, we now turn to the Levy reference to determine the scope and content thereof. Levy discloses a thermoplastic balloon fabricated by the method of drawing (extruding) a polymeric, preferably polyethylene terephthalate (PET) homopolyester, tubing and thereafter expanding the tube. As disclosed at column 4, line 50 et seq., the drawn tubing is inserted into a mold similar to that shown in Figure 1, pinched off at the lower end and subjected to axial tension by the addition of weights. The mold, tubing and weights are then inserted into a liquid medium at 87°C and allowed to heat for about 1 minute, during which time axial orientation occurs. Thereafter, about 200 psi of gas pressure is applied to the tubing, which radially orients the tubing in the mold cavity. This pressurization step lasts about two minutes. The assembly (tubing, mold and weights) is then cooled by immersion into a cold liquid, the pressure is released and the finished balloon is removed from the mold.

In rejecting claim 1 as being anticipated by Levy, the examiner takes the position that the Levy balloon is the same as a balloon prepared by the steps recited in claim 1. We note that Levy does not expressly refer to a step of drying the tubing prior to expanding the tubing. In this regard, however, the step of heating for one minute prior to the application of pressure will, as we see it, inherently dry the tubing to some extent. Therefore, the Levy balloon is, in fact, prepared by the method steps recited in claim 1 and is an oriented hollow balloon of thermoplastic material, as recited in claim 1. Thus, in our opinion, each of the limitations of claim 1 finds full response in Levy. In any case, for the reasons which follow, even if Levy's tubing is not dried prior to the expanding step, we view the examiner's finding that Levy's balloon is the same as a balloon prepared by a method including a step of drying the extruded tubing prior to the expansion step to be reasonable.

It is not apparent to us that a step of drying after the extruding step and prior to the expanding step, per se, results in a different product. From our perspective, a step of drying would appear to affect the final product, if at all,

only to the extent that it changes the moisture content of the tubing or of the final balloon. In this regard, we note that one of ordinary skill in appellants' art at the time of appellants' invention, as evidenced by the discussion of the level of skill in the art in the paragraph bridging pages 6 and 7 of appellants' specification, would have considered the moisture content of the tubing at the time it was subjected to the expansion step to be an important parameter, not the actual presence or absence of a drying step at a particular point in the fabrication process. Thus, in our opinion, the Levy balloon reasonably appears to be the same as a balloon made, for example, by a method including the steps of extruding a hollow tube of thermoplastic material (e.g., PET), having a higher initial moisture content than the PET from which Levy's tubing is extruded, drying the tube to the same moisture content as Levy's tubing and expanding the tube by subjecting the tube to elevated temperature and interior pressure. Also, keeping in mind that claim 1 does not preclude a step of storing the extruded tube in a humid environment for some period of time prior to expanding it, we observe that Levy's balloon would appear to be the same as a

balloon prepared by extruding a hollow tube of PET, drying the tube to a moisture content lower than that of Levy's tubing, storing the tube in a humid environment for a sufficient period of time to restore the tube to its moisture content prior to drying, and then expanding the tube.

As for the "thereby..." clause in claim 1, we note that Levy's balloon has a burst pressure (strength) of from 480 to 525 psi, which is higher than the burst pressure of a reference balloon, such as the control or comparative balloons in appellants' Examples 1-3, which are made according to the method steps recited in claim 1, except for the drying step, and which exhibit burst pressures of about 323 psi (Table 1), 318 psi (Table 2) and 327-328 psi (Table 3).

Appellants point out on page 7 of the brief that appellants use a starting material of a PET having a lower molecular weight and a lower intrinsic viscosity than that of Levy and thus produce a structurally different balloon than that of Levy. While this may be true, the broad terminology "in the same manner," as discussed above, does not require that the reference balloon, relative to which the claimed

balloon has an increased strength, be made from the same starting material as the claimed balloon.

As a practical matter, the PTO is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Thus, the burden of proof on the PTO in making out a case of prima facie obviousness [or anticipation] for product-by-process claims is less than when a product is claimed in the more conventional fashion. In re Fessman, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the PTO has made out a prima facie case that appellants' claimed product and the product of the prior art reasonably appear to be the same, the burden shifts to appellants to prove otherwise. Thorpe, 777 F.2d at 697, 227 USPQ at 966.

For the reasons outlined above, we conclude that a prima facie case has been established that Levy's balloon and appellants' claimed balloon reasonably appear to be the same, thereby shifting the burden to appellants to prove otherwise. As explained in the following discussion, appellants have

failed to meet the burden of proving that Levy's balloon is not the same as appellants' claimed balloon.

Appellants urge that they have shown by the examples in their specification that the addition of a drying step does have an effect on the characteristics of a balloon made from a thermoplastic material in a method similar otherwise to Levy (brief, page 8; reply brief, page 3). We have reviewed the examples in appellants' specification and note that none of the balloons produced and tested was Levy's balloon. For example, all of the balloons tested in Examples 1-3 were made from a PET having a lower intrinsic viscosity than the starting PET material of Levy. Additionally, the wall thickness of each of the balloons tested was on the order of .015 mm, while the wall thicknesses of Levy's balloons were approximately 2-3 times as large (column 2, lines 65-67). Further, the balloons in Examples 1 and 2 and Example 3 were subjected to expansion pressures of 260 psi and 180 psi, respectively, as compared with the 200 psi applied in making Levy's balloon. The balloons in Examples 4-10 were subjected to a programmed dip cycle using different pressures and tensions for blowing different portions of the balloon, while

Levy discloses blowing the entire balloon at the same pressure and tension.

As appellants' examples do not test Levy's balloon, we fail to appreciate how these examples can be construed as establishing that Levy's balloon is not the same as appellants' claimed invention. Even if appellants' examples were sufficient to establish that the addition of a drying step after the extruding step and prior to the expansion step has an effect on the characteristics of a balloon made from a thermoplastic material under the conditions tested, appellants' examples are devoid of any evidence that the addition of a drying step after extrusion and prior to expansion would affect the characteristics of a balloon made under different conditions, such as those disclosed by Levy.⁹ In any case, appellants have not persuaded us that Levy's balloon possesses characteristics which differ from those of a balloon made by the method recited in appellants' claim 1 (albeit perhaps using a starting PET material having a higher moisture content prior to extrusion as compared with Levy or

⁹ We do not share appellants' view that this can simply be presumed (brief, page 8; reply brief, page 3).

storing the extruded tube in a humid environment prior to expanding).

For the foregoing reasons, we shall sustain the examiner's rejection of claim 1, as well as claim 5 which appellants have grouped therewith (brief, page 4), as being anticipated¹⁰ by Levy.

Claims 2-4

Claims 2-4 depend from claim 1 and include further recitations with regard to the moisture content to which the tube is dried prior to the expansion step. Levy does not specify the moisture content of the tubing at the time of the expansion step. Claims 2-4 do not, however, preclude a step of storing the extruded and dried tube in a humid environment prior to the expansion step and, as such, do not dictate the moisture content of the tube at the time it is expanded. Thus, even assuming that the moisture content of the tube at the time it is expanded affects the characteristics of the final product under the operating conditions (e.g., starting

¹⁰ Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

material intrinsic viscosity, tension, pressure, wall thickness, inner and outer diameters, etc.) disclosed by Levy, a fact which has not been established by appellants, Levy's balloon reasonably appears to be the same as a balloon prepared by the process steps recited in the claims. Merely by way of example, Levy's balloon reasonably appears to be the same as a balloon prepared by extruding a hollow tube of PET material, drying the tube to a moisture content within the claimed range and subsequently expanding the tube, albeit *perhaps* with a step of storing the dried tube in a humid environment prior to the expanding step.

For the foregoing reasons, it is our opinion that a prima facie case has been established that the Levy balloon is the same as the balloon recited in claims 2-4. Further, for the reasons cited above with regard to claim 1, the examples in appellants' specification do not persuade us that Levy's balloon does not possess the characteristics of the balloon recited in claims 2-4. Accordingly, we shall sustain the examiner's rejection of claims 2-4 as being anticipated by Levy.

Claims 27-30

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Claims 27, 28 and 30 are substantially the same as claim 1, except that claims 27, 28 and 30, respectively, recite a group of at least 6, 10 and 30 oriented balloons of the type recited in claim 1.

While Levy indicates an objective to provide balloons (column 1, line 40) which exhibit physical properties, for example, toughness, flexibility and tensile strength, superior to those exhibited by prior art balloons, Levy does not expressly disclose fabricating a group of at least 6, 10 or 30 such balloons. Therefore, we cannot sustain the examiner's rejection of claims 27, 28 and 30, or claim 29 which depends from claim 28, under 35 U.S.C. § 102(b) as being anticipated by Levy.

The examiner, however, has alternately rejected claims 27-30 under 35 U.S.C. § 103 as being unpatentable over Levy. It is apparent to us that one of ordinary skill in the art, having read the disclosure of Levy and understanding that Levy's objective was to make balloons having applicability in a variety of surgeries performed at different hospitals and on different patients, would have contemplated a need for at least 30 such balloons and, accordingly, would have been

motivated by the teachings of Levy to fabricate at least 30 of the balloons disclosed by Levy.

With further regard to claim 29, which recites that the tubes are dried to a moisture content of 0.3 weight percent or less, appellants argue that balloons created using the drying step to such a low moisture content would be physically different than those that do not incorporate the drying step and point out that Levy does not address the drying step (brief, page 11). Even if the examples in appellants' specification are sufficient to establish that the moisture content at which the tube is expanded has an appreciable effect on the characteristics of the final balloon in the samples tested, these examples do not establish that this effect is exhibited for a PET having a higher intrinsic viscosity or for the diameters and wall thicknesses fabricated by Levy. Moreover, claim 29 does not preclude a step of storing the dried tube in a humid environment prior to the expanding step and, thus, does not specify the moisture content at the time of expansion. In any case, the salient point here is that appellants simply have not provided evidence that Levy's balloon is not the same as a balloon

prepared in accordance with the method steps recited in claim 29, namely, with the extruded tube being dried to a moisture content as claimed and subsequently (either immediately or after storage for some period of time) expanded.¹¹

In light of the above, we shall sustain the examiner's rejection of claims 27-30 under 35 U.S.C. § 103 as being unpatentable over Levy.

Claims 14 and 15

Claims 14 and 15, like claims 1 and 27, are drafted in product-by-process form and focus on another aspect of appellants' invention, namely, subjecting the tubing to a relatively lower pressure while the body portion is blown than while the first and second waist portions are blown. This aspect of appellants' invention, referred to by appellants as

¹¹ In the event that appellants were to amend their claims to expressly specify the moisture content of the tube at the time of expansion and prove that Levy's balloon is not the same as any balloon made by such a method, appellants and the examiner may wish to consider whether controlling the moisture content of the extruded tube to the levels recited in claims 2-4 and 29 at the time of expansion (e.g., by drying the PET prior to extrusion and expanding immediately after extrusion) would have been obvious to one of ordinary skill in the art as routine optimization of an art-recognized result-effective variable, in light of the admitted recognition in the art at the time of appellants' invention of the importance of moisture content to the balloon-making process (see the paragraphs bridging pages 2-3 and 6-7 of appellants' specification). See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) and In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

"a programmed dipping [dip] cycle," is addressed on pages 3-4, 10 and 18-22 (Examples 4-10) of appellants' specification.

Appellants argue that the use of a relatively lower pressure while the body portion is blown affects the physical characteristics of the balloon by reducing waist and cone thickness and point out that this manner of expansion is not disclosed by Levy (brief, page 9). The examiner does not contest appellants' assertion that sequentially blowing the first waist, body and second waist portions of the balloon and subjecting the balloon to relatively lower pressure while the body portion is blown would physically affect the balloon in an unobvious manner, but insists that such physical effects are not set forth in the claims and are given no weight (answer, page 6). The examiner's position in this regard is not well taken.

To the extent that the process limitations in a product-by-process claim impart or affect physical characteristics of the final product, these physical characteristics must be given weight, notwithstanding that the claim does not explicitly recite such physical characteristics. In this instance, the application of a relatively lower pressure while

blowing the body portion as compared to the waist portions, as recited in claim 14, would appear to us to result in reduced waist and cone thicknesses in relation to the body thickness (see Table 4). As the examiner has neither contested that the recited method steps will result in relatively reduced waist and cone thicknesses nor asserted that the Levy balloon possesses such relatively reduced waist and cone thicknesses, the examiner has failed to establish a prima facie case that the Levy balloon is the same as the balloon recited in claim 14. Thus, we cannot sustain the examiner's rejection of claim 14, or claim 15 which depends from claim 14, as being anticipated by Levy.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1-5, 14, 15 and 27-30 under 35 U.S.C. § 102(b) is affirmed as to claims 1-5 and reversed as to claims 14, 15 and 27-30. The examiner's decision to reject claims 27-30 under 35 U.S.C. § 103 is affirmed.

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No time period for taking any subsequent action in
connection with this appeal may be extended under 37 CFR
§ 1.136(a).

AFFIRMED-IN-PART

IRWIN CHARLES COHEN)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JEFFREY V. NASE)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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